

## CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on November 13, 2000

By: 

Leslie Lindsay

#14

## IN THE UNITED STATES PATENT &amp; TRADEMARK OFFICE

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NOV 13 2000

Applicant: Bitner, et al.

Docket No: 16026.9038

PETITIONS OFFICE

Serial No.: 09/475,958

Group Art Unit: 1655

Filed: 12/30/99

Examiner: B. Sisson

FOR: CELL CONCENTRATION AND LYSATE CLEARANCE  
USING PARAMAGNETIC PARTICLES

INFORMATION DISCLOSURE STATEMENT FILED CONCURRENTLY  
WITH REQUEST FOR CONTINUED EXAMINATION (RCE) PURSUANT  
TO 37 CFR 1.97(1)(b)

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

This Information Disclosure Statement is filed concurrently with a Request for Continued Examination (RCE) of U.S. Serial No. 09/475,958, filed December 30, 1999, which claims priority to provisional application 60/134,156, filed May 14, 1999. The RCE is being filed specifically to allow the Patent and Trademark Office to consider DE 195 12 368A, U.S. Patent No. 6,117,398, PCT Pub. WO 96/31781, and an English translation of DE 195 12 368A.

Pursuant to 37 CFR §§ 1.97-1.98, Applicants submit herewith a listing of documents not previously submitted to or cited by the Patent Office. A copy of each document listed will be submitted under separate cover. With the exception of the above-noted art, all the listed publications were submitted to or cited by the Patent and Trademark Office during the prosecution of a divisional application and are being

brought to the attention of the Patent and Trademark Office in an abundance of caution.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any rights to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicant respectfully request that the listed documents be considered by the Examiner, be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP § 609.

Date:

November 13, 2000

  
Jill A. Fahrlander

Attorney for Applicants

Reg. No. 42, 518

MICHAEL BEST & FRIEDRICH LLP  
One South Pinckney Street, Suite 700  
P. O. Box 1806  
Madison, Wisconsin 53701-1806  
(608) 257-3501

Q:\CLIENT\16026\9038\B0032081 11/08/00

## CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

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## IN THE UNITED STATES PATENT &amp; TRADEMARK OFFICE

PATENT

Applicant(s):	Bitner et al.	Docket No.:	16026-9038
Serial No.:	09/475,958	Group Art Unit:	1655
Filed:	12/30/99	Examiner:	B. Sisson
For:	CELL CONCENTRATION AND LYSATE CLEARANCE USING PARAMAGNETIC PARTICLES		

TRANSMITTAL OF AN INFORMATION DISCLOSURE STATEMENT  
WITH CONCURRENTLY FILED REQUEST FOR CONTINUED EXAMINATION  
APPLICATION (RCE) PURSUANT TO (37 CFR 1.97(b)(1))

Assistant Commissioner for Patents  
Washington, DC 20231

Sirs:

In compliance with the requirements of 37 CFR § 1.97(b)(1) and pursuant to the duty of disclosure of 37 CFR § 1.56, applicants wish to draw the Examiner's attention to the documents listed on accompanying Form PTO-1449. A copy of each document will be submitted under separate cover..

The information disclosure statement submitted herewith is being filed concurrently with a Request for Continued Examination Application.

Respectfully submitted,

Date: November 13, 2000By: 

Jill A. Fahrlander  
Reg. No. 42,518

MICHAEL BEST & FRIEDRICH LLP  
One South Pinckney Street, Suite 700  
P. O. Box 1806  
Madison, Wisconsin 53701-1806  
(608) 257-3501

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:

MICHAEL BEST & FRIEDRICH  
Attn. FRENCHICK, G. /KBR  
One South Pinckney Street  
Suite 700  
Madison, WI 53703  
UNITED STATES OF AMERICA

RECEIVED  
NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

OCT 3 2000

(PCT Rule 44.1)

DOCKETING  
MADISON, WI

FAX RECEIVED

NOV 13 2000

PETITIONS OFFICE

Date of mailing  
(day/month/year)

29/09/2000

Applicant's or agent's file reference

16026/9038

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US 99/31207

International filing date  
(day/month/year)

30/12/1999

Applicant

PROMEGA CORPORATION

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.  
Filing of amendments and statement under Article 19: *— docketed for Nov. 29/00 R.B.W.*

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.35

DOCKETED

Due Date *Dec. 29/00*  
*Suppl. IDS Due.*

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Further action(s): The applicant is reminded of the following: *— docketed for 11/14/00 R.B.W.*

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority

 European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Catherine Humbert

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 18 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

## PATENT COOPERATION TREATY

## PCT

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NOV 13 2000

## INTERNATIONAL SEARCH REPORT

PETITIONS OFFICE

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>16026/9038</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 99/ 31207</b>	International filing date (day/month/year) <b>30/12/1999</b>	(Earliest) Priority Date (day/month/year) <b>14/05/1999</b>
Applicant <b>PROMEGA CORPORATION</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of Invention is lacking (see Box II).

## 4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

## 5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.

☒ None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/1207

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 C12N15/10 C12N5/00 C12N1/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, BIOSIS, PAJ, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 5 681 946 A (REEVE MICHAEL ALAN)          28 October 1997 (1997-10-28)          cited in the application</p> <p>abstract          column 2, line 36 - line 46          column 3, line 14 - line 18          column 6, line 48 - column 7, line 6          column 8, line 10 - line 34          column 11, line 43 - line 47          examples 1,2,6,7          claims 1,3,5,7</p>	<p>1-3,8,9,          11,16,          21-23,          30-32,36</p>
X	<p>DE 195 12 368 A (BOEHRINGER MANNHEIM GMBH)          2 October 1996 (1996-10-02)          abstract          page 5, line 36 - line 45          page 1, line 64 - page 2, line 1</p>	<p>1-4</p>

☒

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

22 September 2000

Date of mailing of the international search report

29/09/2000

Name and mailing address of the ISA  
 European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

Noë, V



## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/31207

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		Relevant to claim No.
Category *	Citation of document, with indication, where appropriate, of the relevant passages	
A	WO 98 31840 A (PROMEGA CORP) 23 July 1998 (1998-07-23) cited in the application the whole document	1-36
A	EP 0 741 141 A (HEWLETT PACKARD CO) 6 November 1996 (1996-11-06) abstract column 8, line 29 - line 33 column 8, line 44 - line 46	7,15,19
A	US 5 898 071 A (HAWKINS TREVOR) 27 April 1999 (1999-04-27)  abstract column 2, line 20 - line 29 column 3, line 5 - line 11 column 3, line 40 column 4, line 59 - line 61 claims 1,6	8,13-15, 21, 23-27, 32-36

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US 99/31207

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5681946 A	28-10-1997	US 5523231 A	04-06-1996
		AT 121748 T	15-05-1995
		CA 2071846 A	14-08-1991
		DE 69109275 D	01-06-1995
		DE 69109275 T	24-08-1995
		DK 515484 T	04-09-1995
		EP 0515484 A	02-12-1992
		WO 9112079 A	22-08-1991
		JP 2703114 B	26-01-1998
DE 19512368 A	02-10-1996	JP 5504095 T	01-07-1993
		WO 9631781 A	10-10-1996
		EP 0819255 A	21-01-1998
WO 9831840 A	23-07-1998	JP 11503315 T	26-03-1999
		US 6027945 A	22-02-2000
		AU 6647598 A	07-08-1998
		BR 9805897 A	24-08-1999
		CA 2249393 A	23-07-1998
		EP 0895546 A	10-02-1999
		JP 11509742 T	31-08-1999
EP 0741141 A	06-11-1996	JP 8301891 A	19-11-1996
US 5898071 A	27-04-1999	US 5705628 A	06-01-1998
		WO 9609379 A	28-03-1996